REMARKS/ARGUMENTS

This application has been carefully considered in light of the Final Office Action of April 29, 2004. In the Final Office Action the Examiner has rejected claims 1-7, 9-11 and 13 under 35 U.S.C. § 102(e) as being obvious and therefore unpatentable over Carlsson et al., US Patent 6,068,860.

In addition to the foregoing, the rejection of claims 1-9 and 12-13, under 35 U.S.C. § 103(a), as being unpatentable over Carlsson et al., when considered in view of Brodin et al., US Patent 5,912,271, is maintained. Further, the rejection of claims 10 and 11 under 35 U.S.C. § 103(a), as being obvious and therefore unpatentable over the primary reference to Carlsson et al. when further considered in view of Brodin et al. and further in view of Cooper et al., US Patent 4,442,872, has also been maintained.

It is respectfully submitted that the present invention which is directed to a method of prolonging a local topical effect on the skin of a pharmaceutically or cosmetically active substances is not taught by the prior art as suggested.

The present invention is directed to a method of prolonging a local topical effect of an active substance in a topical cream or lotion prepared using an oil-in-water emulsion carrier wherein

a galactolipid material is an emulsifier. Further, claim 1 has been amended to positively recite the prolonging of a local topical effect as a positive method step.

The primary reference to Carlsson et al. discloses a mixture in which galactolipids form liposomes or gels. The formulations taught contain glucocoroticoid, foscarnet, and galactolipids as set forth in example 5. Example 5 is directed to antiviral and antiflammatory formulation. The reference is specifically directed to improving the site-directed administration of the foscarnet by utilizing the galactolipid material.

In the reference, under the heading "Biological Test" three different formulations are tested. Formulation "A" contains galactolipids, Formulation "B" contains phospholipids, and Formulation "C" is with a conventional cream based carrier. According to the tests, Formulation "A" gave the most rapid penetration of the active substance with Formulation "B" being the slowest.

According to test, subsurface accumulation and concentration of the active is enhanced by the use of the galactolipid material as in Formulation "A". Formulation "B" demonstrated that the phospholipid formulation brings about a slower penetration of the foscarnet through the stratum. It is therefore, respectfully submitted that one of ordinary skill in the art would look to

Formulation "B" as being preferred to obtain a "prolonged effect" of an incorporated active substance as opposed to Formulation "A"

The Examiner, however, argues that a drug's effectiveness is inherently increased as rapid accumulation allows for higher concentrations and thus continued dosing at a site. Applicants respectfully disagree that rapid concentration is the same as to prolonging an effect of an active substance. The Examiner quotes from column 4, lines 11-15 of the reference that the composition can "sustain a high concentration of foscarnet in the living epidermis". It is respectfully submitted that the use of "sustain" in this phrase refers to the fact that the formulation can per se contain a high amount of the active substance and does not suggest prolonging the effect of the active substance at the site of concentration.

Applicants further suggest that increasing rapid concentration can not equate to prolonging the local effect of an active substance because prolonging relates to the effect of the substance at any concentration. Therefore, at any given concentration, the effect of the active substance would be prolonged utilizing the teachings of the present invention. Thus, at higher concentrations of the active, the effect would be prolonged over what would normally be anticipated.

In view of the foregoing, and as the reference to Carlsson

et al. is silent as with respect to extending the local effect of an active at any given concentration, the reference does not teach the methodology of the present invention and should not form the basis for a combination rejection with the secondary references.

The reference to Brodin et al. discloses pharmaceutical preparations comprising local anaesthetic agents. In the reference, although examples are given, none disclose creams or lotions formulated using oil-in-water emulsions wherein a galactolipid material is the emulsifier. Therefore, it is respectfully submitted that one of ordinary skill in the art would not look to modify the Carlsson et al. reference with the teachings of the reference to Brodin et al. wherein such use of the galactolipid material is not anticipated.

Further, the reference to Brodin et al. only cites pharmaceutical preparations for pain management including agents for local anaesthetic treatment. It is respectfully submitted that the reference does not suggest nor teach the prolongation effect of active substances generally in a cream or lotion prepared utilizing oil-in-water emulsion as is taught in the present application. The teaching of Brodin et al. is that generally water-free or very sparse water lipid formulations containing sphingolipids, or optional galactolipids, of

anesthetics may provide a reduce onset time and extend the duration of the anesthetic agent. It is respectfully submitted that this would not teach one of ordinary skill in the art to conclude that galactolipids could be used as taught in the present invention in oil-in-water based creams or lotions to prolong the local effect of an active agent in the cream or lotion.

The reference to Cooper et al. has also been considered. This reference, however, only teaches the use or inclusion of a corticosteroid, however, does not suggest nor teach any type of oil-in-water emulsion as a base for a topical cream or lotion wherein a galactolipid material is an emulsifier.

As claim 1 of the present application has been specifically amended to include a positive method step of "prolonging", and in view of the differences between the present invention and the prior art as set forth above, reconsideration of the grounds for rejection is respectfully requested and favorable consideration and allowance of claims 1-13 is solicited.

Should the Examiner have any questions regarding this response or the allowability of the claims, it would be appreciated if she would contact the undersigned attorney-of-record at the telephone number shown below for further expediting the prosecution of the application.

It is also respectfully requested that this amendment, after final, be entered for purposes of placing the application in condition for allowance or, in the alternative, to support an appeal.

As this response is being filed after the shortened statutory period, a separate request for extension of time is submitted herewith. Any deficiencies in the extension of time fees may be charged to Deposit Account No. 04-1577.

Respectfully submitted,

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